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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/224,781	01/04/1999	BARRY M. LIBIN	1059-007	3261

7590 04/01/2002

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EXAMINER

ROSE, SHEP K

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 04/01/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/224781

Applicant(s)

L181N

Examiner

S1688

ROSE

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 5/17/01
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☐ Claim(s) 1 7 18025 27032 is/are pending in the application.
- Of the above claim(s) 7 18025 30 31 (renewed 132 31+32) is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1 23 24 25 27030 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 7 18025 30 31 (renewed 132 31+32) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

The May 7, 2001 response elects fungus disease infections treated with triclosan and cetylpyridinium chloride and refers to a span hour (not of record) Declaration (in 09/168950) of both on candida albicans.

The May 7, 2001 response to the October 5, 2000 and March 2, 2000 Office actions inadvertently fail, as required, to identify the claims that correspond to the elections as well as those that do not even if the requirements are traversed, (as stated on page 11 of the March 2, 2000 Office action requiring (on page 10) an election of:

(a) one species of a cationic antimicrobial agent species from the Markush groups of claims 9, 19 and 27 and

(b) one species of a disease selected from one of:

mucositis (claim 7)

a fungus disease infection; or

a herpetic infection, which involve separate and burdensome fields of search.

Markush group practice and separate and burdensome searches are involved herein.

Claim 26 is cancelled. Dependent claims 27 to 30 depend on cancelled claim 26.

Claims 23 (amended to add—and a cationic antimicrobial correspond--), 24, 25 correspond to the elected species, while claim 1 is generic thereto.

Claims 7, 18 to 25, 30 and 31 (renumbered, (Rule 126) as claims 31 and 32 are withdrawn, Rule 142(B) as non-elected subject matter.

Dependent claims 27 to 30 are objected to (as noted above) as being dependent on cancelled claim 26.

Applicant inadvertently cancelled claim 26 in the August 7, 2000 *response*

The USPTO examiner has made of record and applied five (5) foreign patents, set forth on pages 8 and 9 of the March 2, 2000 Office action; each describing triclosan (T) admixed with encompassed species of cationic anti-microbial agents including "CPC" cetylpyridinium chloride, as elected, in Hill and Kao, or of triclosan with other cationic agents in VEB and Gluck (I-II), well as seven (7) literature articles treating candida Albicans fungal infection (as elected) with chlorhexidine (CHX) cationic anti-microbial (alone), and applicant cited Takaoka, GB 2160099 treats the fungus infection of athletes foot with triclosan (alone).

(A) Hill et al, EP 679390 (11/95) describes a topical spray for herpes, cold sores (column 1, lines 1 to 18) painful eruptions on skin and mucous membranes comprising a mixture of two or more (column 2, lines 25-26) of triclosan and cetylpyridinium chloride "CPC" as elected, column 2, lines 20-21 etc., (meeting claims 1, 23, 24, 25, 27 to 30).

Kao, EP 843002 (5/98) describes and claims anti-dandruff deodorant germicide shampoos applied topically to scalp, body and skin comprised of CPC (as elected) claim 5 (example 10, page 17), cetylpyridinium chloride, and triclosan, claim 6, and an anionic surfactant (solubilizer), (meeting claims 1, 23, 24, 25, 27 to 30).

VeB, DD 221080 (4/85), Gluck (I-II) (WO 86/05391(9/86), (I) (page 8, lines 32 to 39, claim 4 mixtures of two or more of triclosan and chlorhexidine digluconate or Benzalkonium chloride, (II) claim 7—triclosan and chlorhexidine gluconate or (page 1,

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line 35 to page 2, line 6) benzalkonium chloride each meet claims 1, 23, 24, 25, 27, 29 and 30 in describing topical antiseptic germicidal fluid compositions of triclosan and such encompassed species of cationic agents.

Applicant's August 7, 2000 remarks are clearly erroneous, and not agreed with in stating that Hill makes "no mention" of the use of triclosan in combination with a cationic agent for the treatment of a herpetic infections. The cold sores are herpes infections therein.

Livingston, Canada 2,132,688 (3/96) describes herpes infections (page 4, lines 15-27) (page 7, line 12) treated with triclosan (page 3, lines 7, 8) (claim 1) and benzalkonium chloride vaginal disinfectant, meeting claim 1, which recites herpetic infections or fungal infections. Applicant's remarks have inadvertently overlooked Livingston's claimed combination of triclosan (named as its chemical synonym) and benzalkonium chloride explicitly stated to treat herpes infections, and the plain fact is that claim 1 is not limited to the elected fungus infections but also encompass treating herpetic infections, and the plain fact that claim 1 is not limited to the elected fungus infections but also encompass treating herpetic infections. Claims 1, 23, 24, 25, 27, 29 and 30 are met by applying the composition of Livingston.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 23, 24, 25, 27 to 30 rejected under 35 U.S.C. 103(a) as being unpatentable over Takoaka, GB 2160099 (treating fungus infections with triclosan (alone), taken with one of the chlorhexidine for candida fungus literature references. Budtz-Jorgensen (Dec. 1977), Kostiala (1982), Ferrati et al (I-II) April (1987) (June 1987), or Poland (1987) (chlorhexidine for herpes, fungi, candida) and in further view of anyone of: Hill et al, Livingston Kao, Gluck (I-II) and VEB (details as noted above) combining triclosan with encompassed species of cationic antimicrobial agents for expected additive co-action.

The responsive (August 7, 2000 page 3) remarks concede the fact that the literature references (noted above) employ chlorhexidene against oral candida fungus, arguing that "there is" "no mention of triclosan", and that Takaoka does in fact treat athlete's foot fungus infections with triclosan, arguing "no suggestion to use a cationic agent with triclosan", but on page 4 of the remarks it is clearly admitted that triclosan is combined with cationic agents in each of: Livingston and Hill (both treat herpes infections as in claim 1, Gluck (I-II) and VEB.

The combination of the known antifungal triclosan with the known antifungal cationic agents—chlorhexidine benzalkonium, or cetylpyridinium is prima facie obvious for expected additive co-action of both action agents.

OBVIOUS COMBINATION CASE LAW

As stated in In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA-1980):

“... It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court explained in Crockett, 126 USPQ 186, 188 (CCPA-1960), the idea of combining them flows logically from their having been individually taught in the prior art.

Likewise, see In re Pinten, 173 USPQ 801, 803 (CCPA 1972); and In re Susi, 1969 USPQ 423, 426 (CCPA-1971).

Additionally, claim 1 is met by treating herpes infections with both triclosan and the cationic agent, as in Hill et al and Livingston (details as noted above). There is no “Declaration of Norman Spainhour” of record herein attesting to “unexpected results, which flow from the combination of triclosan and cetylpyridinium chloride on candida albicans,” as argued on page 2 of the May 7, 2001 remarks.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday, and Thursday 7:30am-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-4544 for regular communications and (703) 305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



SHEP K. ROSE
PRIMARY EXAMINER
GROUP 1202

Rose: mv
March 26, 2002